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A5R RHEC

(56) Documents Cited
GB 2291505 A GB 2287882 A EP 0013613 A1
US 4729377 A US 4709704 A US 4391279 A

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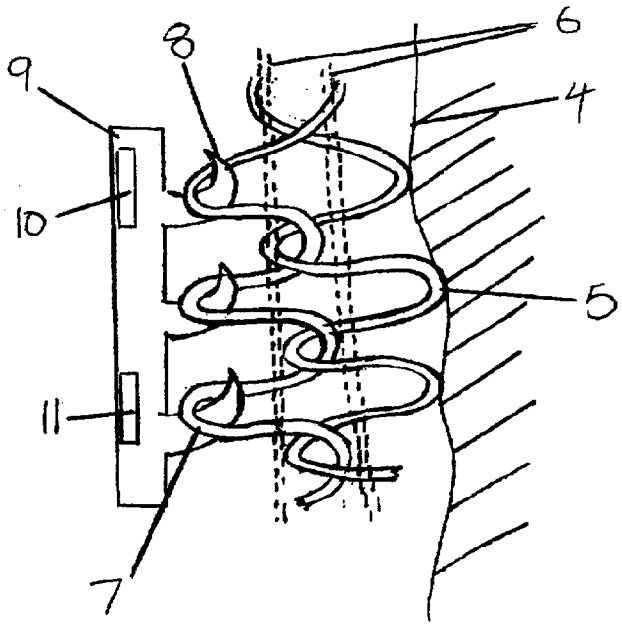
(54) Abstract Title
Health monitoring garment

(57) A health monitoring garment which employs a means of conducting electricity from the surface of the skin, though the fibres of a fabric to another fabric, which is removably attached to it and contains a microprocessor, telemetry and a power source to monitor and transmit ECG data of a person wearing the clothing, as illustrated in Figure 2. Removabilty enables the garment to be washed and the electronics to be kept separate from the washing and tumble drying process. The same system can be used in reverse to effect cardiac pacing or defibrillation or to deliver other forms of electrically conveyed healing such as tissue repair.

FIG. 2



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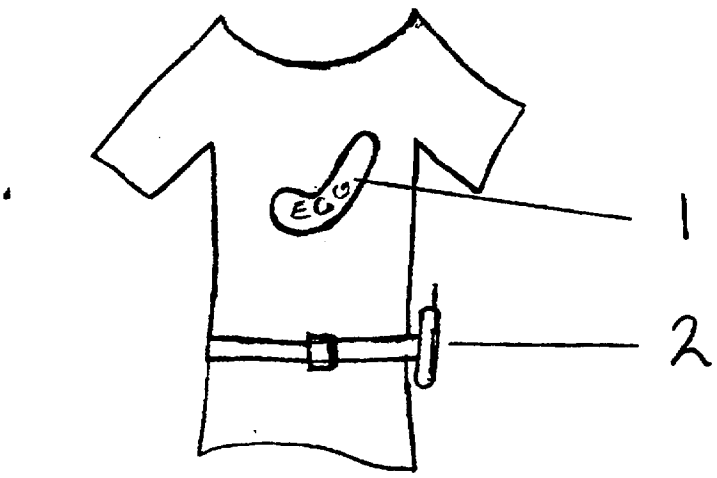
The claims were filed later than the filing date but within the period prescribed by Rule 25(1) of the Patents Rules 1995.

FIG 1



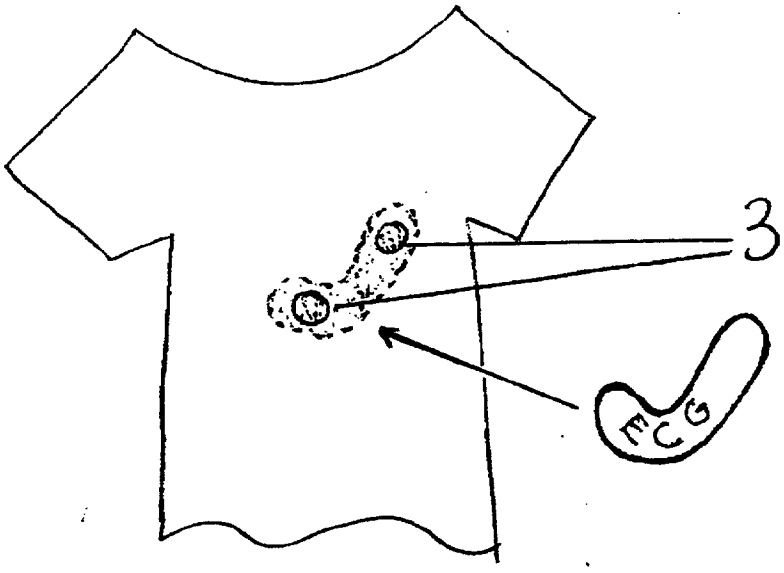


FIG. 2.

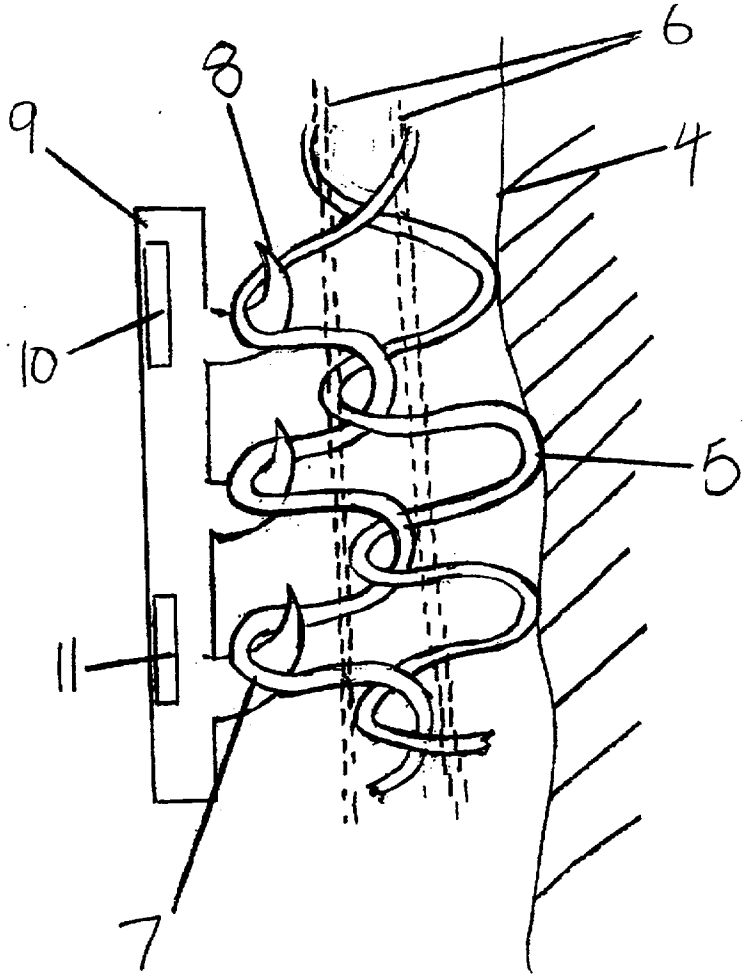


FIG 3

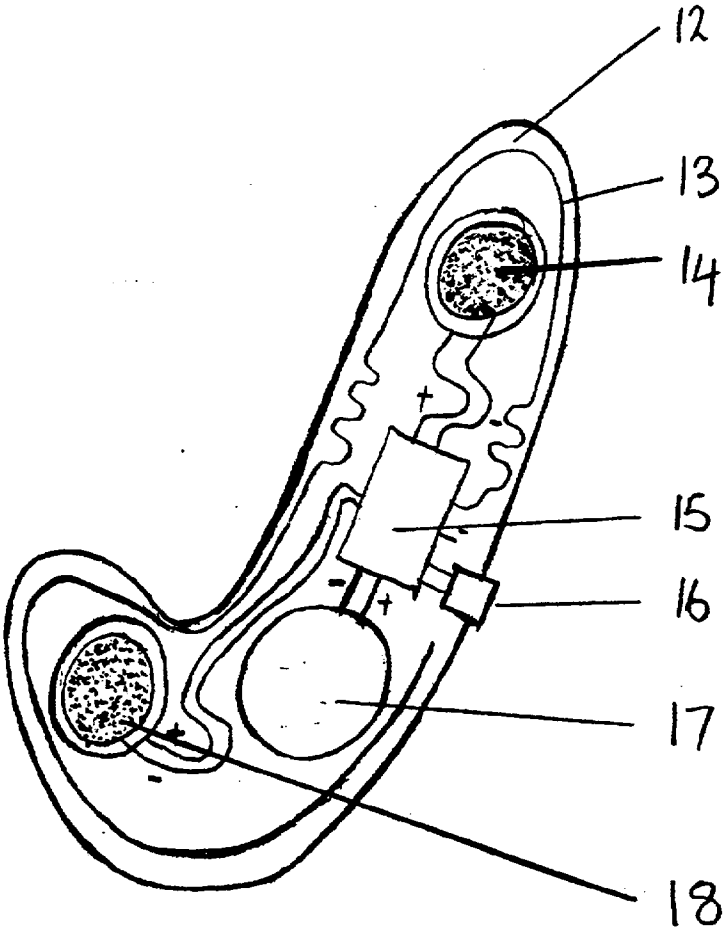
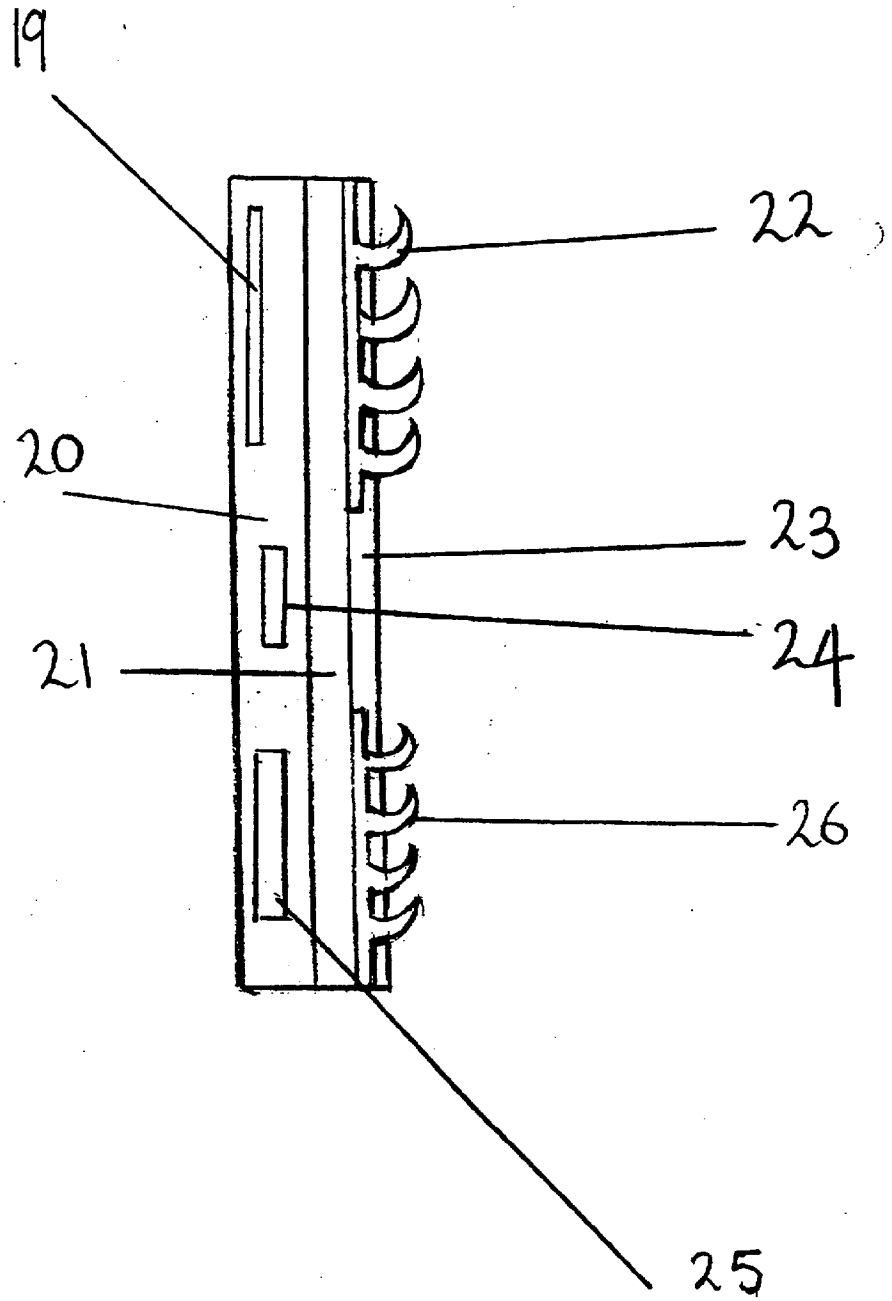


FIG. 4



Health Monitoring

The present invention relates to health monitoring and it is especially concerned with monitoring the electrophysiological cardiac and respiratory and tissue vital signs of a human or animal subject. Electrophysiological cardiac monitoring of humans is usually referred to (in English) as the Electro Cardiogram (ECG) or the EKG in the USA. Electrophysiological respiratory monitoring is generally referred to as impedance monitoring and a third form of electrophysiological monitoring of the very small electrical impulses from human tissue, muscle or other body cells, which are usually measured by SQUID biomagnetmometers to produce three-dimensional current distribution images of the heart, for example, is known as Biomagnetic Computed Tomography.

There are many commonly used ambulatory methods of monitoring electrophysiological information such as the Holter, pendant, chest-strap and credit card heart monitors. Additionally some clothing includes microchips and fibre optics to ambulatorily monitor the heart. However all these current systems of electrophysiological monitoring are not wholly non-invasive in that they need to be regarded as special medical devices. The wearing of a medical device has undesirable psychological implications attached to it in that few people like to admit to either themselves or others that they require a machine as part of their everyday lives. Additionally there are the ergonomic restrictions of the discomfort and inconvenience associated with the attachment of electrodes, gels, straps and belts to the human body. Hence the traditional ECG or respiratory monitor creates and undesirable intrusion into everyday life.

It is one of the of the objects of the present invention to monitor electrophysiology in a less obtrusive, cumbersome and inconvenient manner than with known devices.

According to one aspect of the invention there is provided a system for monitoring the electro-physiological and electro-respiratory vital signs of a human or animal subject, comprising a vest or undershirt for wear by the subject in the form of a garment that has stretch both longitudinally and laterally of the subject's body to fit the body closely and constructed from conductive and non conductive yarns. These can be knitted by such machines as a Double Loop Automatic Needle Selection Circular Knitting Machine. These conductive yarns may be knitted in the form of loops on the outside of the garment immediately opposite and integrally conjoined with the corresponding internal conductive loops on the inside of the garment where by the internal conductive loops touch the human or animal skin. The internal and external loops are entwined during the knitting process so as to transfer electrical impulses from the inside to the outside the garment. This provides an alternative to the use of adhesive electrodes used by traditional ECG monitors. The knitted conductive yarns are hereinafter referred to as "Knitted Electrodes". In order to insulate one pair of Knitted Electrodes from another, a separate group conductive yarns is fed into the circular knitting machine for each pair of electrodes, interspaced with non-

conductive yarns.

According to a second aspect of the invention there is provided a sensor pad in the form of a common carrier, hereinafter referred to as the "ECG Patch" which is removably attaheable to the conductive on the outside of the garment. The ECG Patch has an attachment means on its underside which may be in the form of a friction-fit mechanism similar to the hooks marketed under the brand name "Velcro". The hooks provided on the ECG Patch Patch can be made by the same knitting or molding process as that required for traditional Velcro hooks. However in this electrical application the hooks are a fabricated from a conductive material such as an electrically conductive polymer or polymers loaded with conductive particualtes, for molded applications; or conductive yarns made from such materials as stainless steel, copper, polymer and carbon fibre for knitted applications.

By the interaction between the Knitted Electrodes and the conductive hooks located on the underside of the ECG Patch the electrical impulses present on the human skin are passed to a microprocessor and the wire-free transmission means located inside the ECG Patch.

The benefit of using the common carrier hook-and-loop wire-free transmission means, the ECG Patch, is that it can be used as a releasable, tear-off patch, to be removed prior to washing. This would enable the garment to be washed, tumble dried and ironed without exposing electronic package to undue water ingress, heat or friction, thereby allowing it be treated like any other normal, washable, everyday garment.

According to a third aspect of the invention there is provided in the ECG Patch sufficient electronic processing power and the appropriate algorithms to give a warning of impending severe illness such as a heart attack or asthma attack; the said warning can be in the form of a flashing light and or audible warnings emanating from the ECG Patch.

According to a fourth aspect of the invention there is provided a transformer in the ECG Patch an auxiliary electric power source, which, upon receiving a command from the microprocesor can deliver electrical shocks to the subject via the Knitted Electrodes to which it is attached. These electric shocks may be mild so as to provide a cardiac pacing function or they may be more powerful, such as 200-300 volts, to provide a defibrillating function. (Recent research has demonstrated that low power shocks can be used to restore normal heart rhythm in a fibrillating or arrhythmetic patient instead of high power 2,000 to 3,0000 volt shocks.) Additional battery power could be provided by an auxiliary battery located in the ECG Patch or by wire connection to an auxiliary battery located somewhere on the subject such as in a pocket.

According to a fifth aspect of the invention there is provided in the ECG Patch a wire-free transmission and receiving means such as a radio or infra red system in

order to send and receive cardio-respiratory data to a palm-top computer/mobile telephone worn by the subject. By this means data can be processed using the greater processing power available in a palm-top computer than that available in the ECG Patch. Additionally the mobile telephone can be used to send data for remote analysis by an Analytical Science Medical Research Center or the appropriate physician anywhere on earth. The center could access and cross reference data from hundreds or thousands of patients, downloading millions of hours of cardiac events and thereby provide the epidemiological data for long term research and development necessary for the compilation of universally applicable warning signals for critical conditions such as Sudden Cardiac Death or asthma attacks. The mobile telephone can designed to receive warning data from the Analytical Medical Science to enable the palm-top computer to update or modify pacing or defibrillating instructions effected by the ECG Patch.

It is envisaged that the palm-top computer will be fitted with a removable memory card which can be used to poste cardiac and respiratory data to a physician in the event that the telephone system does not function correctly.

According to a seventh aspect of the invention it is conceivable that separate defibrillating Knitted Electrodes may be incorporated in the ECG patch whose function is only to administer electric shocks to the patient.

According to a eighth aspect of the invention there is provided a conduction enhancement means for the Knitted Electrodes. In the event that better conductivity is required than that inherent in conductive polymer yarns, or conductive stainless steel yarns or conductive polymer yarns entwined with cotton yarns, which when placed against the skin in the manner described by "Knitted Electrodes", absorb sweat and provide adequate ECG and respiratory signals (as proved by experiment by the applicant), it is possible to improve conductivity by a fabric-finishing process such as cutting and brushing the inside loops of the Knitted Electrodes and the application of an ideally water-based spray-on conductive gel, of a medium similar to antiperspirant. This adheres to the fibers, is deformed by the pressure of the garment against the skin and increases the area of conductivity between each fiber and the skin. Alternatively, in the event that a patient is not suitable for low voltage defibrillation, a standard high voltage adhesive defibrillation patch can be adhered to the patent and attached by wire to the control-electronics in the ECG Patch and by other wires to an appropriate high-voltage power source.

According to a nine aspect of the invention there is provided a remotely programmable electronic personal information tag inside the ECG Patch to record the user's name, address and primary health data.

The method and system of the invention are particularly useful for the long term, continuous and 24 hour-a-day monitoring of heart patients, particularly those who may be susceptible to Sudden Cardiac Death of which some 800,000 people die every year in Europe and USA. By this means the subjects may be monitored by

a vest, or undershirt that to them appears very similar to normal apparel, with none of the discomfort, stigma or psychological burdens associated with traditional ECG or respiratory monitors. By wearing the invention - the ECG vest- continuously, particularly at night when most of the potentially fatal cardiac events are known to occur, the computer databases linked to it, either remotely by telephone or quasi remotely by the palm-top computer worn by the patient or directly by the ECG Patch's on board ASIC (the ASIC being equipped with the appropriate microprocessor and event-identifying algorithms) the invention has a variety of life-preserving opportunities to process sufficient data to forewarn patients of an imminent heart attack and if necessary deliver arrhythmia-regulating or defibrillating electric current.

Methods and systems for monitoring electrophysiological and electrorespiratory vital signs of a subject in accordance with the present invention will now be described, by way of example, with
reference to the accompanying drawings in which:-

Figure 1
Figure 1 is the general embodiment of the ECG vest where 1, is the releasable common carrier, the ECG Patch patch, 2 is the patient's mobile phone and computer with which it communicates and 3, illustrates the Knitted Electrodes beneath an ECG Patch that has been removed. For the purpose of simplicity only two of several areas of conductive loops are shown. These conductive loop areas could encompass the body if required.

Figure 2
Figure 2 is a cross sectional representation to illustrate how the electrical impulses present on the surface of human skin at 4, can be passed into a knitted or woven garment configuration comprising 5, the internal conductive loops which touch the skin; 6, the foundation loops made from a non conductive yarn which hold the internal and external loops together; 7, the external conductive loops which are attached to conductive Velcro at 8. 9 is a representation of the releasable patch which contains the electronic parts including the ASIC 10, and battery 11.

Figure 3
Figure 3 is a plan of the releasable ECG patch wherein 12, is the periphery of the patch which can be of any shape or design suitable to encompass the Knitted Electrodes; 13, is the antenna which is connected to the ASIC; 14, is one of the two conductive Velcro parts; 15, is the Applied Specific Integrated Circuit, and transformer containing the electronic elements sufficient to transmit the ECG and Respiratory impedance signals; to receive commands from the nearby mobile phone or to receive internal commands generated by ASIC-on-board algorithms and to act on those commands in respect to the provision of electric shocks to the conductive Velcro. 16 is an electric socket with sufficient connections to enable the ASIC/TRANSFORMER assembly to receive auxiliary electrical power and to communicate defibrillateing instructions to standard adhesive defibrillator

electrodes which may be applied to the patient in the event that the low voltage defibrillation capacity of the invention needs to be supplemented by high voltage defibrillation. 17, is the battery power supply to the ASIC and 18 is the second conductive Velcro pad. Wiring connections are show by lines with + and - symbols attached to them.

Figure 4

Figure 4 is a cross sectional representation of the ECG patch wherein 19 is a programmable electronic label to hold the patient's personal data; 20, is the outside protective layer, which may have designs and decorations on it, 21 is the first inner electrical insulation layer, 22 is one of the conductive Velcro pads, 23 is a second non-conductive layer which may also be constructed from Velcro, but of the non-conductive type. 24 is the ASIC; 25 the battery and 26 is the second conductive Velcro pad. The pads and electronic parts may be stuck with non-conductive adhesive attached to the outside protective layer. Materials shown at 20, 21, and 23 can be made from elastic components so that they stretch and the electrical connections between each conductive Velcro patch and the ASIC can be designed so that they too can accept the flexing movement of this ECG and Respiratory patch to accommodate the chest expansion and contraction as the wearer breaths.

CLAIMS

1. A means of conducting electricity between two fabrics so that an electric current present on the surface of one fabric can be transmitted through it to the surfaces of a second fabric so as to provide, for example, a health monitoring garment whereby the one fabric placed against the skin of and animal or human subject collects an electrophysiological signal such as an ECG and passes it to another removable fabric, where the latter may contain a wireless transmitting means.

2. A means of conducting electricity as in Claim 1 where the first fabric is a knitted or woven material presenting loops of conductive yarn and the second fabric is made from an electrically conductive hook substrate such as the male part of a hook and loop fastener commonly referred to as Velcro and made from a conductive polymer so that the conductive hooks embed firmly into the raised loops of the first fabric, thereby providing the dual functionality of passing electricity from one to another and also the ability to remove one fabric from the other.

3. A means of conducting electricity as in Claim 2 where the first fabric is a knitted or woven material presenting loops of conductive yarn and the second fabric is made from another conductive material and held against the first fabric by such means as of poppers, buttons, tape or any other attachment means.

4. A means of conducting electricity as in Claim 2 wherein the electrically conductive hook substrate is elastic made, for example, by punching a latticework of hexagonal holes in the substrate.

5. A means of conducting electricity as in Claim 1 and 2 where groups of conductive yarns and groups of receptive conductive hooks are insulated from one another so that the electric current emanating from the skin an animal or human subject can be picked up from more than one location to emulate, for example a three lead or 22 lead ECG.

6. A means of conducting electricity as in Claim 5 where conductive yarns in a knitted fabric are separated from one another by knitting the conductive yarns in separate rows on a common non-conductive base cloth.

7. A means of conducting electricity as in Claim 6 where the conductive loops of a knitted fabric are presented as separate islands of raised loops, which would appear to be spots or any other design as can be achieved, for example, with a variable sinker height circular knitting machine.

8. A means of conducting electricity as in Claim 2 where several hook substrates are presented in groups, such as spots to co-inside, for example, with the spots described in Claim 6, wherein the hook-spots are insulated from one another by mounting them in a non-conductive substrate such as rubber or plastic.

9. A means of conducting electricity as in Claim 1 to Claim 8 where the conductive hooks, or each group of conductive hooks are attached to a microprocessor and wireless signal

transmission means such as, for example, a radio or infra red device to communicate the electrophysiological data emanating from the skin to a remote place.

10. A means of conducting electricity as in Claim 1 and 9 where the electrophysiological data may be transmitted to a computerised device worn by the subject, or to a remote computer and provided with appropriate software to interrogate the electrophysiologial data so as to classify physiological performance of a human or animal heart.

11. A means of conducting electricity as in Claim 10 whereby information received by a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to administer an electric shock through the fabrics described in Claim 1 to instigate cardiac pacing or cardiac defibrillation.

12. A means of conducting electricity as in Claim 11 whereby information received by a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to administer an electric current through the fabrics described in Claim 1 to instigate the healing process of damaged tissue, muscles or biological attachments thereto of a human or animal subject.

13. A means of conducting electricity as in Claim 11. whereby information received by a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to administer an electric current through the fabrics described in Claim 1 to apply electromagnetic energy to a man made chemical substance, such as for example, a drug to combat cancer whereby such application will stimulate the drug to become effective only in a precise area within the electromagnetic field.

14. A means of conducting electricity as in Claim 11. whereby information received by a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to apply electric energy to activate acoustic sensors by means of, for example, piezo ceramic electric transducers, through the fabrics described in Claim 1 and thereby to resonate a man made chemical substance such as, for example, an enzyme designed to dissolve the fatty deposits common to arterial sclerosis, and to activate the enzyme only in the precise area within the predetermined range of the aformentioned acoustic energy.

15 A mans of conducting electricity as in Claims 7 and 6 wherein the raised loops are cut to increase surface area and may have a conductive liquid applied to them, both to increase conductivity.

Amendments to the claims have been filed as follows

CLAIMS

1. A means of conducting electrophysiological energy from the skin-surface of a human or animal subject to a computing and transmissions means whereby the energy can be conducted by an otherwise normal every-day garment by the inclusion of electro-conductive yarns, groups of which are electrically insulated from one another, to similarly insulated groups electro-conductive friction-fit hooks, (such as conductive polymer Velcro), of a removable patch containing the computing and transmission means so as to provide a measurement of the ECG/EKG.

2. A means of conducting electrophysiologial energy as in Claim 1 where the normal every-day garment is a knitted or woven material presenting insulated groups of loops of conductive yarn wherein their isolation is achieved by securing the conductive loops in a knitted or woven foundation of non-conductive yarns, such may be achieved with variable height automatic sinker selection circular knitting machine.

3. A means of conducting electrophysiologial energy as in Claim 1and 2 where conductive yarns in a knitted fabric are presented as a group of raised loops insulated from another group one another by knitting the two, or multiple groups on separate rows of non-conductive base cloth.

4. A means of conducting electrophysiologial energy as in Claims 1,2 and 3 where the conductive loops of a knitted fabric are presented as separate islands of raised loops, which would appear to be spots or any other design as can be achieved, for example, with a variable sinker height circular knitting machine.

5. A means of conducting electrophysiological energy as in Claims 1,2,3 and 4 where groups of conductive yarns and groups of receptive conductive hooks are insulated from one another so that the electric current emanating from the skin an animal or human subject can be picked up from more than one location on the skin to emulate a multi-lead EC/EKG.

6. A means of conducting electrophysiological energy as in Claims 1 to 5 wherein the raised loops are cut to increase surface area and may have a conductive liquid applied to them to increase conductivity.

7. A means of conducting electrophysiological energy as in Claim 1 wherein the removable patch contains an alternative conductive material to friction-fit hooks such as randomly constructed mass of entwined conductive yarn or other cloth, paper, rubber or other electroconductive substrate.

8. A means of conducting electrophysiological energy as in Claim 1 wherein the removable patch is secured not only by friction fit Velcro hooks but also, or alternatively, by poppers, buttons, string or other attachment means.

9. A means of conducting electrophysiological energy as in Claim 1 wherein the electrically conductive removable patch is elastic and able to conform to the movement of the human or

animal chest, such as for example by constructing the friction-fit Velcro substrate from a layer of such substrate pierced with a latticework of holes so that the substrate can stretch.

10. A means of conducting electrophysiological energy as in Claim 1 to 9 where the groups of conductive hooks on the removable patch are attached to a microprocessor and wireless signal transmission means such as, for example, a radio or infra red device to communicate the electrophysiological data emanating from the skin to a remote place.

11. A means of conducting electrophysiological energy as in Claim 1 to 10 where the electrophysiological data may be transmitted to a computerised device worn by the subject, or to a remote computer and provided with appropriate software to interrogate the electrophysiological data so as to classify physiological performance of a human or animal subject.

12. A means of conducting electrophysiological energy as in Claim 11 whereby information received by a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to administer an electric shock through the fabrics described in Claim 1 to10 to instigate cardiac pacing or cardiac defibrillation.

13. A means of conducting electrophysiological energy as in Claim 10,11 and 12 whereby a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to administer an electric current through the fabrics described in Claim 1 to 8 to instigate the healing process of damaged tissue or muscles of a human or animal subject.

14. A means of conducting electrophysiological energy as in Claim 10 whereby by a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to administer an electromagnetic field of energy through the fabrics described in Claim 1 to 8 into the body of a human or animal subject to act upon a man made chemical substance such as a drug suspended or travelling within the tissues or the blood of the body, whereby such application will stimulate the chemical substance to perform a specific function only in the precise area encompassed by the said electromagnetic field, so as for example to activate tumour killing or tissue ablating drugs only in the area where they are desired to function.

15. A means of electrophysiological energy as in Claim 11 whereby information received by a local or remote computer can instruct a microprocessor and electrical supply means located on a human or animal subject to activate acoustic propagating material applied to or part of yarns described in claims 1 to 8 such as, for example, piezo ceramic material to resonate and thereby act upon a man made chemical substance suspended or travelling within the tissues or the blood only within the predetermined range of the aforementioned resonating acoustic energy.

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Application No:	GB 9905931.3	**Examiner:**	Eamonn Quirk
Claims searched:	1-15	**Date of search:**	13 September 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5R (RHEC) G1N(NECG, NESS)

Int Cl (Ed.7): A61B (5/00, 5/0408)

Other: Online: WPI, EPODOC, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2 291 505 A	(Healthcare Technology Limited)	
A	GB 2 287 882 A	(Lowry)	
A	EP 0 013 613 A1	(Johnson & Johnson)	
A	US 4 729 377	(Bio Stimu-Trend)	
A	US 4 709 704	(The Kendall Company)	
X	US 4 391 279	(Clinical Data Inc.) Whole Document	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.